

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SEP 16 1998

Vickie Forster
AgrEvo USA Company
2711 Centerville Road
Wilmington, DE 19808

Dear Ms. Forster:

This is in regard to AgrEvo's consultation on genetically modified canola that you initiated with the Agency on May 29, 1998, specifically transformation events MS8 and RF3. According to AgrEvo, the canola line MS8 has been modified to express the male sterile gene (barnase) and the herbicide glufosinate-ammonium resistance gene (bar). MS8 is used to produce F1 hybrids. The canola line RF3 has been modified to contain the fertility restorer gene (barstar) and the herbicide glufosinate-ammonium resistance gene (bar). Upon crossing MS8 with RF3, the fertility of the oilseed rape progeny will be restored. The use of these two lines allows for the production of seed that is 100% hybrid, 100% fertile, and 100% glufosinate tolerant.

You submitted a summary of your safety and nutritional assessment of the AgrEvo hybrid canola containing transformation events MS8 and RF3. These communications informed FDA of the steps taken by AgrEvo to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that AgrEvo has concluded that the canola lines are not materially different in composition, safety, or other relevant parameters from canola currently on the market, and that they do not raise issues that would require premarket review or approval of FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF 0057 and will be maintained by the Office of Premarket Approval.

Based on the information AgrEvo has presented to FDA, we have no further questions concerning the AgrEvo hybrid canola containing transformation events MS8 and RF3 at this time. However, as you are aware, it is AgrEvo's continued responsibility to ensure

Page 2 – Forster

that foods the firm markets are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan M. Rulis, Ph. D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

cc:	HFS-13	HFS-200	HFS 206
	HFS-246	HFV-200	HFS-225
	HFV-221	HFV-228	BNF000057